

**Introduction**

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

**1) Submitter  
name, address,  
contact**

Varian, Inc.  
25200 Commercentre Drive  
Lake Forest, CA 92630  
(949) 770-9381

Contact: Lorna Gamboa

Date Prepared: May 11, 2005

**2) Device Name**

Proprietary Name: OnTrak TesTcard

Panel: Toxicology

<b>Classification Name:</b>	<b>Product Code</b>	<b>Regulation Number</b>
Enzyme Immunoassay, Amphetamine	DKZ	862.3100
Enzyme Immunoassay, Barbiturate	DIS	862.3150
Enzyme Immunoassay, Benzodiazepines	JXM	862.3170
Enzyme Immunoassay, Cocaine and Cocaine Metabolite	DIO	862.3250
Fluorometry, Morphine	DJJ	862.3640
Enzyme Immunoassay, Phencyclidine	LCM	Unclassified
Enzyme Immunoassay, Cannabinoids	LDJ	862.3870
Gas Chromatography, Methamphetamine	LAF	862.3610
Radioimmunoassay, Tricyclic Antidepressant Drugs	LFG	862.3910

**3) Predicate  
Device**

We claim substantial equivalence to this currently marketed device:

On Trak TesTcard 9, K012396, 11/05/2001  
On Trak TesTcard 9, K050321, 04/18/2005

**4) Device  
Description**

The OnTrak TesTcard assays contained in this submission are in vitro diagnostic tests intended for the qualitative detection of drug or drug metabolite in urine. The TesTcard devices simultaneously test for the presence of multiple drugs or drug metabolites. The TesTcard profile (cutoff) consists of amphetamines (d,l-amphetamine 1000 ng/mL), barbiturates (secobarbital 200 ng/mL), benzodiazepines (oxazepam 100

ng/mL), cocaine metabolite (benzoylecgonine 300 ng/mL), methamphetamine (d-methamphetamine 500 ng/mL), morphine (morphine 300 ng/mL), PCP (phencyclidine 25 ng/mL), tricyclic antidepressants (TCA) (imipramine 1000 ng/mL) and THC (11-nor- $\Delta^9$ -THC-9-carboxylic acid 50 ng/mL).

The TesTcard assays are based on the principle of microparticle capture inhibition. The test relies on the competition between drug, which may be present in the urine being tested, and drug conjugate immobilized on a membrane in the test chamber.

When the TesTcard contacts the urine sample, the sample is absorbed into the TesTcard sample pad. The absorbed sample travels through the reagent strips contained in the device by capillary action. In the reagent strip, the sample rehydrates and mobilizes antibody-coated blue microparticles. The microparticle-urine suspension continues to migrate through the reagent strip and comes in contact with the immobilized drug conjugates. In the absence of drugs in the urine, the antibody coated microparticles bind to the drug conjugates and blue bands are formed in the result areas.

When drugs are present in the specimen, they bind to the respective antibody-coated microparticles. If sufficient drug is present, the microparticles are inhibited from binding the appropriate drug conjugate and no blue band is formed in the result area below the drug name. A positive specimen causes the membrane to remain white.

An additional antibody/antigen reaction occurs at the "VALID" area. The "TEST VALID" blue band forms when antibodies imbedded in the reagent membrane bind to the antigen on the blue microparticles. The presence of the "TEST VALID" band indicates that the test has completed, the reagents in the "TEST VALID" area are valid, and the results are ready to interpret.

#### 5) Technological Characteristics

All drug test strips contained in the TesTcard products have been previously reviewed by FDA under the 510(k) numbers indicated in Section 3 of this summary.

Like the predicate device, TesTcard devices utilize microparticle capture inhibition.

#### 6) Substantial Equivalence

The TesTcard devices have the same intended use and incorporate the same fundamental scientific technology as the predicate device.

	<u>Testcard</u>	<u>Predicate</u>
<b>Intended Use</b>	Qualitative detection of drugs in urine	Same
<b>Scientific Technology</b>	Microparticle capture inhibition	Same
<b>Sample Matrix</b>	Urine	Same



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

**JUN 8 - 2005**

Ms. Lorna Gamboa  
RA/QA Manager  
Varian, Inc.  
25200 Commercentre Drive  
Lake Forest, CA 92630

Re: k051235  
Trade/Device Name: OnTrak TesTcard™  
Regulation Number: 21 CFR 862.3100  
Regulation Name: Amphetamine test system  
Regulatory Class: Class II  
Product Code: DKZ, DIS, JXM, DIO, LAF, DJJ, LCM, LFG, LDJ  
Dated: May 11, 2005  
Received: May 13, 2005

Dear Ms. Gamboa:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

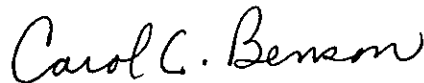
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

Page 2 –

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in cursive script that reads "Carol C. Benson".

Carol C. Benson, M.A.  
Acting Director  
Division of Chemistry and Toxicology  
Office of *In Vitro* Diagnostic Device  
Evaluation and Safety  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number: K051235

Device Name: OnTrak TesTcard™

### Indications for Use:

The OnTrak TesTcard menus are various combinations of the different drugs that are listed below. The TesTcard products are in vitro diagnostic tests for the qualitative detection of drug or drug metabolite in urine. It simultaneously tests for the presence of multiple drugs or drug metabolites. The TesTcard profile (cutoff) consists of the following:

	<u>Cutoff Concentrations:</u>
Amphetamines (d,l-amphetamine):	1000 ng/mL
Barbiturates (secobarbital):	200 ng/mL
Benzodiazepines (oxazepam):	100 ng/mL
Cocaine metabolite (benzoylecgonine):	300 ng/mL
Methamphetamine (d-methamphetamine):	500 ng/mL
Morphine (morphine):	300 ng/mL
PCP (phencyclidine):	25 ng/mL
Tricyclic Antidepressants (TCA)(Imipramine):	1000 ng/mL
THC (11-nor- $\Delta^9$ -THC-9-carboxylic acid):	50 ng/mL

TesTcard products provide only preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result.

Prescription Use ✓  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)



Division Sign-Off

Office of In Vitro Diagnostic  
Device Evaluation and Safety

510(k) K051235

Page 1 of 1